भारतीय मानक
Indian Standard

IS 6356 : 2021

टूथपेस्ट — विशिष्टि

(चौथा पुनरीक्षण)

Toothpaste — Specification

(Fourth Revision)

ICS 71.100.70

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

November 2021 **Price Group 8**

FOREWORD

This Indian Standard (Fourth Revision) was adopted by the Bureau of Indian Standards after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

This standard was originally issued in 1971 and first revised in 1978 when the changes were made in the requirements of fineness and a test for hard- and sharp-edged particles was included in place of test for abrasion.

In the second revision in 1993, toothpaste was classified as fluoridated and non-fluoridated toothpaste. New requirements for toothpaste stability, microbial purity, spreadability, ease of extrusion, fluoride ion for fluoridated toothpaste and tube inertness were included. Lower limit for pH was raised in line with International standard, keeping in mind the safety aspect of toothpaste. Requirements for expiry date and labelling key ingredients on containers were also incorporated in this revised version.

In the third revision in 2001, considerable help was derived from various overseas standards.

Relevant parts of these standards were incorporated in the standard, keeping in mind the specific needs in the Indian context. Definitions for dentifrice and toothpaste were included from ISO 11609.In line with the new emerging technologies, such as use of soft agglomerates/capsules, the fineness specifications and test method were modified in this version.

The toothpaste, when used in a normal manner, shall not cause injury to the teeth, gums, and mucous membrane of the mouth or the body in general. The role of toothpaste is to clean the surface of teeth and also to prevent/ reduce the incidence of oral dental diseases like caries, gingivitis or periodontal diseases. The use of toothpaste improves the oral hygiene. Hence toothpaste with active ingredients like fluoride, triclosan, etc, which help in improving oral hygiene are part of this specification.

Toothpaste formulations are designed to have optimal abrasivity to effect cleaning action without hurting soft tissues or tooth enamel by way of excessive abrasivity. Relative dentine abrasivity (RDA) is recognized in most of the International Standards as the measure to determine this parameter. RDA is, therefore, recommended as a type test in this standard. The abrasivity of the toothpaste shall not exceed the limits specified when tested as per procedure given in Annex H. The abrasivity measurement methodology has been based on 1S0 11609.Since RDA measurement facility is currently not available in India, a simpler abrasion test using a photographic paper is being developed. This procedure may be adopted in future after completing the studies and establishing validation with RDA.

Toothpaste containing fluorides have been unequivocally proven to be effective in caries control but under certain conditions excessive ingestion of fluoride may contribute to fluorosis. Keeping both the aspects in mind , the Ministry of Health and Family Welfare has imposed a restriction on limit of fluoride ion in toothpaste. While retaining the maximum available fluoride level at 1000 ppm for fluoridated toothpaste, a simpler method for fluoride analysis was included in the third revision of the standard.

In the fourth revision of the standard no changes have been made on the maximum limit on heavy metal content expressed as lead in tooth paste. However a requirement of Mercury, with a limit of one ppm has been added. While a method for estimation of heavy metals expressed as lead has been provided in Annex D of this standard, alternate, validated methods, such as Atomic Absorption Spectrophotometry (AAS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) may also be used. However, in case of dispute, the method described in Annexure D of this standard will be the referee method.

Requirements for fineness have been modified for both fluoridated and non-fluoridated toothpastes.

No stipulations have been made regarding the composition of tooth paste, however, it is essential that the tooth paste formulations do not contain any ingredient in sufficient concentration to cause a toxic or irritating reaction when used in the mouth. Nor shall it be harmful in normal use, keeping in mind that small amounts may be ingested inadvertently

(*Continued to third cover*)

Indian Standard

TOOTHPASTE — SPECIFICATION

(Fourth Revision)

1 SCOPE

This standard prescribes the requirements and the methods of sampling and test for toothpaste.

2 REFERENCES

The Indian Standards referred in this standard have been listed below.. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard:

IS No.	*Title*
264 : 2005	Nitric acid (*second revision*)
265 : 2021	Hydrochloric acid (*fourth revision*)
460 (Part 1) : 2020	Test sieves: Part 1 Wire cloth test sieves (*third revision*)
2088 : 1983	Methods for determination of arsenic (*second revision*)
IS 3958 : 1984	Methods of sampling cosmetics (*second revision*)
4707	Classification of cosmetic raw materials and adjuncts
(Part 1) : 2020	Dyes colours and pigments (*second revision*)
(Part 2) : 2017	List of raw materials generally not recognized as safe for use in cosmetics (*second revision*)
14648 : 2011	Methods of test for microbiological examinations of cosmetics
4011 : 2018	Method of test for safety evaluation of cosmetics (*second revision*)
16913 : 2018	Methods of test for cosmetics and determination of heavy metals (arsenic, cadmium, lead and mercury) by atomic absorption spectrometry

3 DEFINITIONS

3.1 Dentifrice — A dentifrice is any substance or combination of substances specially prepared for the public for cleaning the accessible surfaces of teeth.

3.2 Toothpaste — A toothpaste is defined as a dentifrice in the form of a smooth, semisolid, homogeneous mass containing acceptable ingredients such as abrasives/polishing agents, surface active agents, humectants, binding agent, and other appropriate substances for oral health maintenance. The product can be opaque, transparent, or combination thereof, coloured or white, packed in a suitable container from which it can be extruded in the form of a continuous mass.

4 TYPES

The toothpaste shall be of either Type 1 or Type 2:

a) Type 1 — Non-fluoridated; and
b) Type 2 — Fluoridated.

5 REQUIREMENTS

5.1 Composition

A toothpaste shall not contain mono or disaccharides, for example, sucrose or other readily fermentable carbohydrates. All the raw materials used shall conform to respective Indian Standards wherever they exist. A list of ingredients conventionally used in the manufacture of toothpaste is given in Annex A for information only.

The dyes and pigments used in manufacture of toothpaste shall comply with the provisions of 1S 4707 (Part 1).

Ingredients other than dyes and pigments used in formulation of toothpaste shall comply with the provisions of IS 4707 (Part 2).

For safety evaluation of novel ingredients used in formulation of a toothpaste, the toothpaste shall comply to IS 4011.

5.2 Dispensing

The paste shall extrude from the collapsible tube or any other suitable container in which it is packed, at 27±2 °C in the form of continuous mass with the application of normal force, without the application of excessive force which would cause injury to the tube or the container. It shall be possible to extrude bulk of the contents from the container or the tube starting from the crimped end of the tube by rolling the tube gradually.

5.3 Stability

The toothpaste shall not show any physical sign of deterioration during normal conditions of storage and use. When subjected to a temperature of 45±2 °C for a period of 28 days the toothpaste shall meet the requirements of the standard. When cooled to a temperature of 5 °C for 1hour, after taking out and pressing tube, the paste shall be found extrudable from the tube and meet the requirement of this standard.

It is not advisable to keep the toothpaste tube without the cap. If left open for a long duration, the toothpaste might lose moisture on account of evaporation and harden.

5.4 Packaging Material Inertness

The collapsible tubes or any other suitable container used for packaging of toothpaste shall not corrode, deteriorate or cause contamination of the toothpaste during normal condition of storage and use. When subjected to a temperature of 45 ± 2 °C for 10 days, the paste shall then be examined visually by extruding part of the contents. The internal surface of the tube shall be examined after slitting it open and removing the remaining contents. There should be no sign of corrosion, chemical attack or other damage.

5.5 Acceptance Test

The toothpaste shall also comply with the requirements given in Table 1 when tested according to the methods given in Annex B to Annex G, as per reference made in col 5 of Table 1.

5.6 Expiry Date

Shelf life shall be declared by the manufacturer for all types of toothpaste.

Manufacturing date (month and year) is recommended to be mentioned on tube and carton. The declaration of expiry date shall be as per requirements of *Drugs and Cosmetics Act* and Rules of India, and any other relevant regulation. During the shelf life the product will meet the requirement of the standard.

5.7 Additional Requirements for ECO-Mark

5.7.1 *General Requirements*

5.7.1.1 The product shall conform to the requirements for quality, safety and performance prescribed under **5.7.1.2** to **5.7.1.5**.

5.7.1.2 All the ingredients that go into formulation of cosmetics shall comply with the provisions of IS 4707 (Part 1) and IS 4707 (Part 2). The product shall also meet specific requirements as given in the standard.

5.7.1.3 The product package shall display a list of key ingredients in descending order of quantity present.

5.7.1.4 The product shall not be manufactured from any carcinogenic ingredients.

5.7.1.5 The manufacturer shall produce to BIS environmental consent clearance from the concerned State Pollution Control Board as per the

Table 1 Requirements for Toothpaste

(*Clause* 5.5)

Sl No.	Characteristic	Requirement for		Method of Test Ref to Annex
		Non-fluoridated	Fluoridated	
(1)	(2)	(3)	(4)	(5)
i)	Fineness:			B
	a) Particles retained on 150 micron IS Sieve, percent by mass, *Max*	3.0	3.0	
	b) Particles retained on 75 micron IS Sieve, percent by mass, *Max*	3.5	3.5	
ii)	pH of aqueous suspension	5.5 to 10.5	5.5 to 10.5	C
iii)	Heavy metals (as lead), parts per million, *Max*	20	20	D
iv)	Arsenic (as As_2O_3), parts per million, *Max*	2	2	E or IS 16913
v)	Foaming power, ml, *Min* [1)]	50	50	F
vi)	Available Fluoride ion, parts per million, *Max*	50	1000	G
vii)	Mercury (as Hg), parts per million, *Max*	1	1	IS 16913
vii)	Microbial counts:			
	a) Total viable counts per gram, *Max*	1000	1000	IS 14648
	b) Gram negative pathogens per gram, *Max*	Absent	Absent	IS 14648

[1)] Applicable to foaming toothpaste only.

provisions of the *Water* (*Prevention and Control of Pollution*) *Cess Act, 1977* and the *Air* (*Prevention and Control Pollution*) *Act,* 1981 along with the authorization, if required under the *Environment* (*Protection*) *Act*, 1986 and the Rules made thereunder, while applying for ECO-Mark. Additionally, provisions of the *Drugs and Cosmetics Act*, 1940 and the Rules thereunder shall also be complied with.

5.7.2 *Specific Requirements*

Heavy metals calculated as lead (Pb), arsenic ($As_2 0_3$), and mercury shall not exceed 20 ppm, 2 ppm, and 1 ppm respectively when tested by the respective method prescribed in Indian Standards.

6 ABRASIVITY (TYPE TEST)

The toothpaste shall not exceed the limits of dentin abrasivity that of 2.5 times when tested as per the procedure given in Annex H. It may be noted that type test is recommended to be done on the formulation only once to pass the above criterion. This test need not be done for each and every batch. However, the type test is a must again if the abrasive system is changed in the formulation. It is not required for the new formulation as long as abrasive components are not changed.

7 PACKING AND MARKING

7.1 Packing

Toothpaste shall be packed in collapsible tubes or in any other suitable containers like sachets, pumps or other suitable dispensing systems. When packed in containers, the containers shall be properly sealed and have a leak-proof cap or closure. The containers, if necessary, may further be packed in cartons or any other suitable packaging material.

7.1.1 The material for product packaging shall meet the parameters evolved under the scheme of labelling environment friendly packaging/packaging materials.

7.2 Marking

7.2.1 The labelling and marking of toothpaste shall comply with the statutory requirements under Cosmetic Rules, 2020, Legal metrology and any other relevant statutory requirement, In addition the tubes and the cartons shall be legibly marked with the following information:

a) Name and type of toothpaste;
b) Name and Address of the manufacturer;
c) Net mass or volume of the material in the tube;
d) Batch number, in code or otherwise;
e) Month and year of manufacture;
f) Fluoride ion content for Type 2 toothpaste in ppm;
g) Expiry date or "Best use before. . .. " (Month and year to be declared by the manufacturer);

NOTE — This requirement is exempted in case of pack sizes of 10g/25 ml or less and if the shelf life of the product is more than 24 months; and

h) Foaming/non-foaming; and
j) List of key ingredients.

NOTE — This is exempted in case of pack sizes of 30 g or less.

7.2.2 *BIS Certification Marking*

7.2.2.1 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

7.2.2.2 If the product is covered under ECO-Mark (optional), it shall be suitably marked with ECO-Mark logo besides Standard Mark. The label may clearly specify that ECO-Mark is applicable to the contents or the package or both, as the case may be. If the product package is not separately covered under ECO Mark scheme, it shall be clearly mentioned on the product that ECO-Mark label is applicable to contents only.

8 SAMPLING

8.1 Representative test samples of the material shall be drawn as prescribed in IS 3958.

8.2 Number of Tests and Criteria for Conformity

The tests for abrasivity, stability and container's inertness shall be type tests and shall be performed for product approval whereas tests for dispensing, fineness, *p*H, heavy metals, arsenic, foaming power, fluoride content, mercury and microbial counts shall be carried out on each batch for acceptance of the product.

8.2.1 The type tests shall be repeated in the event of change in the basic formulation or whenever there is a change in the type of container being used. However, the acceptance tests shall be performed on each and every batch.

8.3 A batch may be defined as consisting of any quantity of toothpaste manufactured in a single mix at one time.

8.4 The lot shall be declared as conforming to requirements of the specification, if all the test results on each individual sample meet the requirements prescribed in **5.2** to **5.6**.

9 QUALITY OF REAGENT

Unless specified otherwise, pure chemicals and distilled water (*see* IS 1070) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities, which affect the results of analysis.

ANNEX A

(*Clause* 5.1)

INGREDIENTS CONVENTIONALLY USED IN THE MANUFACTURE OF TOOTHPASTE

A-1 Raw material used in toothpaste formulation falls into the following categories:

a) Polishing agents;
b) Surface active agents;
c) Humectant;
d) Binding agent; and
e) Others as per IS 4707 (Part 1) and IS 4707 (Part 2).

A-1.1 Polishing Agents

The principal polishing agents generally used are one or more of those given below:

1. Calcium carbonate;
2. Magnesium carbonate;
3. Dicalcium phosphate;
4. Insoluble sodium metaphosphate;
5. Hydrated alumina;
6. Aluminium hydroxide;
7. Aluminium/alumino silicate;
8. Alumina;
9. Alumina fumed;
10. Calcium phosphate;
11. Calcium pyrophosphate;
12. Dicalcium phosphate dehydrate;
13. Kaolin;
14. Magnesium silicate;
15. Potassium metaphosphate;
16. Silica gel or precipitated;
17. Silica fumed;
18. Silica hydrated;
19. Sodium aluminium silicate;
20. Sodium bicarbonate;
21. Sodium metaphosphate;
22. Hydroxyapatite;
23. Zirconium silicate;
24. Sodium polymetaphosphate;
25. Tungsten carbide;
26. Pumice;
27. Silicon carbide;
28. Magnesium silicate;
29. Agglomerates (mainly consisting of one or more of the polishing agents); and
30. Others as per IS 4707 (Part 1) and IS 4707 (Part 2).

A-1.2 Surface Active Agents

The surface active agent(s) generally used are one or more of those given below:

1. Soap;
2. Sodium ricinoleate;
3. Sodium sulphoricinoleate;
4. Sodium lauryl sulphate;
5. Sodium alkyl sulphoacetate;
6. Sodium salt of sulphated monoglyceride;
7. Sodium lauryl sarcosinate;
8. Sodium alpha olefm sulphonate;
9. Coco-amido-propyl-betaine;
10. Sodium dodecyl benzene sulphonate;
11. Sodium Iauryl sulphoacetate;
12. Coconut monoglyceride sulphonates;
13. Dioctylsodiurn-sulphosuccinate;
14. Magnesium lauryl sulphate;
15. Sodium alkyl benzene sulphonate;
16. Sodium alkyl sulphate;
17. Sodium lauryl ether sulphate;
18. Coco-betaine; and
19. Others as per IS 4707 (Part 1) and IS 4707 (Part 2).

A-1.3 Humectants

The humectants generally used are one or more of those given below:

1. Glycerol;
2. Sorbitol;
3. Maltitol;
4. Mannitol;
5. Polyethylene glycol;
6. Propylene glycol;
7. Lactitol;
8. Xylitol; and
9. Others as per IS 4707 (Part 1) and IS 4707 (Part 2).

A-1.4 Binding Agents

The binding agents generally used are one or more of those given below:

1. Gum tragacanth;
2. Gum karaya;
3. Sodium alginate;

4. Sodium carboxymethyl cellulose;
5. Gelatine;
6. Guar gum and its derivatives;
7. Xanthan gum;
8. Carraghenates
9. Carboxy methyl cellulose;
10. Magnesium aluminium silicate;
11. Starch;
12. Hydroxy propyl cellulose;
13. Hydroxy ethyl cellulose;
14. Carbopol;
15. viscarin;
16. Polymers (propylene oxide-ethylene oxide-blockcopolymer); and
17. Others as per IS 4707 (Part 1) and IS 4707 (Part 2).

A-1.5 Other Substances

1. Fluorides of sodium and stannous;
2. Monofluorophosphate of ammonium, potassium and sodium;
3. Sweeteners, saccharine sodium, aspartame;
4. Petroleum jelly-silicon defoaming compounds and mineral oil 5. Colouring agents;
5. Colouring agents;
6. Essential oils;
7. Flavoring agents;
8. Astringents;
9. Preservatives;
10. Antibacterial agents;
11. Antiplaque agents;
12. Antitartar agents;
13. Whitening agents;
14. Anti caries agents;
15. Calcium glycerophosphate;
16. Granules/agglomerates;
17. Anti gingival agents;
18. Other as per IS 4707 (Part 1) and IS 4707 (Part 2); and
19. Desensitizing agents.

ANNEX B

[*Clause* 5.5 *and Table* 1, *Sl No.* (i)(a)]

DETERMINATION OF FINENESS

B-1 OUTLINE OF THE METHOD

Squeeze the toothpaste and feel the presence of the particles/agglomerates/granules. Subject the toothpaste suspension to an ultrasonic treatment and pass through fineness test. Ultrasonification loosens out the soft agglomerates into the constituent materials.

B-2 APPARATUS

B-2.1 Ultrasonic Bath — Trans-O-sonic compact model or equivalent, (60 + 10 Watts power with 35 + 5 KHz Ultrasonic frequency, 1-2 Watts/inch 2 power density, L × B × H : 225 × 125 × 60 mm tank).

B-2.2 Sieves — 75 and 150-microns [conforming to IS 460 (Part 1)].

B-2.3 Glass beakers (250 ml, 500 ml) and stirring rods.

B-3 PROCEDURE

B-3.1 Determination of Particle Feel on Butter Paper

Extrude the paste about 15 to 20 cm length each from at least ten collapsible tubes on a butter paper, test the paste by pressing it along its entire length by a finger for the presence of particles. The toothpaste suspension should be subjected to an ultrasonic treatment followed by a fineness test as described in **B-3.2** and **B-3.3**.

B-3.2 Determination of Particle Size on 150 Micron IS Sieve

Place about 20 g of the toothpaste, accurately weighed, in a 250 ml beaker. Add 200 ml of water and allow to stand for about 30 min with occasional stirring until the toothpaste is completely dispersed free of

toothpaste/gel flocks trapping the agglomerates. Transfer the beaker in an ultrasonic bath. Fill the ultrasonic bath (2 litre capacity) to about three-fourth height with water. Clamp the above beaker in the centre of the bath keeping about 1 cm clearance from the bottom of the bath and subject ultrasonification for 10 min to completely loosen out the constituents.

Transfer this suspension quantitatively to a 150 micron IS Sieve and wash by means of a slow stream of running tap water and finally with a fine stream from a wash bottle until all the matter that can pass through the sieve has passed, let the water drain out and then dry the sieve containing the residue in an oven. If there is any residue on the sieve, carefully transfer it to a tarred watch glass and dry it to constant mass in an oven at 105 ± 2 °C.

B-3.3 Determination of Particle Size on 75 Micron IS Sieve

Weigh accurately about 20 g of the toothpaste and proceed as in **B-3.2**, using a 75 micron IS Sieve. If there is any residue on the sieve carefully transfer it to a tared watch glass and dry it to constant mass in an oven at 105 ± 2 °C.

B-4 CALCULATION

$$\text{Material retained on 150-micron} = \frac{M_1 \times 100}{M}$$

IS Sieve, percent by mass.

where

M_1 = mass in g, of residue retained on the sieve; and

M = mass in g, of the material taken for the test.

ANNEX C

[*Clause* 5.5 *and Table* 1, *Sl No*. (ii)]

DETERMINATION OF *p*H

C-1 PROCEDURE

Dispense 10 g of the toothpaste from the container in a 50 ml beaker and add 10 ml of freshly boiled and cooled water (at 27 °C) to make 50 percent aqueous suspension. Stir well to make a thorough suspension. Determine the *p*H of the suspension within 5 min, using a *p*H meter.

ANNEX D

[*Clause* 5.5 *and Table* 1*, Sl No.* (iii)]

DETERMINATION OF HEAVY METALS

D-1 OUTLINE OF THE METHOD

The colour produced with thioacetamide reagent in test solution is matched against that obtained with standard lead solution.

D-2 APPARATUS

D-2.1 Nessler Cylinders — 50 ml capacity.

D-2.2 Weighing Scale — 0.0001 g accuracy.

D-2.3 Volumetric Flasks — 100 ml capacity.

D-2.4 Platinum Crucible

D-2.5 Pipette — 2, 10 ml.

D-3 REAGENTS

D-3.1 Concentrated Hydrochloric Acid — *See* IS 265.

D-3.2 Concentrated Nitric Acid — *See* IS 264.

D-3.3 Hydrofluoric Acid

D-3.4 Dilute Acetic Acid — 6 M (342 ml of glacial acetic acid diluted to 1 000 ml with water).

D-3.5 Glycerol Mixture — Take 15 ml of 1MNaOH and add 5 ml water and 20 ml of 85 percent glycerol. Mix well.

D-3.6 Thioacetamide Reagent — Weigh 80 mg of thioacetamide and add 2 ml water to it. Shake to dissolve. Add 10 ml glycerol mixture, heat on water bath for 20 s, cool and use immediately.

D-3.7 Lead Nitrate Stock Solution — (100 ppm as Pb) — Dissolve 0.1599 g of lead nitrate in water containing 1ml of nitric acid and makeup the solution to 1 000 ml.

D-3.8 Standard Lead Solution — (10 ppm as Pb) — Dilute 10 ml of lead nitrate stock solution with water to 100 ml. Each ml is equivalent to 0.01 mg of Pb.

D-3.9 Acetate Buffer (3.5 *p*H) — Dissolve 25 g of ammonium acetate in 25 ml water and add 38 ml of 7 M hydrochloric acid. Adjust the *p*H to 3.5 either 2M hydrochloric acid or 6 M ammonia and dilute to 100 ml with water.

D-4 PROCEDURE

D-4.1 Place 2g of toothpaste sample accurately weighed in a platinum dish and incinerate for about 2 hours at 525 to 550”C. Cool and add 1 to 2 ml of hydrochloric acid and 0.5 ml nitric acid and evaporate to dryness on the steam bath. Dissolve the residue in 5 ml hot water, evaporate to dryness and treat it with hydrofluoric acid. Evaporate again to dryness. Dilute it with water (about 50 ml). Filter the solution, if necessary, with suction through a fine fritted glass filter and dilute the filtrate and washing to 100 ml in a graduated flask. This solution shall be used for tests given in **D-4.2** and **E-3** as test solution.

D-4.2 Transfer 25 ml of test solution prepared in **D-4.1** in a 50 ml Nessler cylinder, add further 2 ml of test solution and 2 ml acetate buffer (*p*H = 3.5) and mix well. Add 1.2 ml of thioacetamide reagent, mix, and immediately dilute with water to 50 ml and allow to stand for 2 min.

D-4.3 In the second Nessler cylinder, place 1 ml standard lead solution (*see* **D-3.8**) and add 2 ml of test solution. Dilute with water to 25 ml, and add 2 ml acetate buffer (*p*H 3.5). Mix, add 1.2 ml of thioacetamide reagent, and immediately dilute with water to 50 ml. Allow to stand for 2 min. Compare the colour produced in the two Nessler cylinders.

D-5 RESULT

The limit prescribed in Table 1 shall be taken as not having been exceeded if the intensity of colour produced in the test solution is not greater than that produced in the second Nessler cylinder which is a control test.

ANNEX E

[*Clause* 5.5 *and Table* 1, *Sl No*. (iv)]

DETERMINATION OF ARSENIC

E-1 OUTLINE OF THE METHOD

Arsenic present in a solution of the material is reduced to arsine, which is made to react with mercuric bromide paper. The stain produced is compared with a standard stain.

E-2 REAGENTS

E-2.1 Mixed Acid — Dilute one volume of concentrated sulphuric acid with four volumes of water. Add 10 g of sodium chloride for each 100 ml of the solution.

E-2.2 Ferric ammonium sulphate solution dissolve 64 g of ferric ammonium sulphate in water containing 10 ml of mixed acid and make up to one litre.

E-2.3 Concentrated Hydrochloric Acid — *See* IS 265.

E-2.4 Stannous Chloride Solution — Dissolve 80 g of stannous chloride ($SnCl_2.2H_20$) in 100 ml of water containing 5 ml of concentrated hydrochloric acid.

E-3 PROCEDURE

Carry out the test as prescribed in IS 2088, adding into the Gutzeit bottle, 2 ml of ferric ammonium sulphate solution, 0.5 ml of stannous chloride solution and 25 ml of stannous chloride solution, 0.5 ml of stannous chloride solution and 25 ml of sample solution as prepared in **D-4.1**.

For comparison, prepare a stain using 0.001 mg of arsenic trioxide.

ANNEX F

[*Clause* 5.5 *and Table* 1, *Sl No*. (v)]

DETERMINATION OF FOAMING POWER

F-1 GENERAL

Strict attention shall be paid to all details of the procedure in order to ensure concordant results. Particular care should be taken to shake the cylinder exactly as described.

F-2 OUTLINE OF THE METHOD

A suspension of the material in water is taken in a graduated cylinder and given 12 shakes under prescribed conditions. The volume of the foam formed is observed after keeping the cylinder for 5 min.

F-3 APPARATUS

F-3.1 Graduated cylinder (250 ml), glass stoppered; with graduations from 0 to 250 ml, with 2ml divisions, overall height about 35 cm and the height of the graduated portion about 20 cm.

F-3.2 Graduated cylinder (100 ml), with graduations from 0 to 100 ml, with 1 ml divisions.

F-3.3 Thermometer, of range 0 to 110 °C.

F-4 PROCEDURE

F-4.1 Weigh about 5 g of the toothpaste accurately in a 100-ml glass beaker, add 10 ml of water, cover the breaker with a watch glass and allow to stand for 30 min. This operation is carried out to disperse the toothpaste.

NOTE — Ensure that the toothpaste is completely dissolved, warming the aqueous suspension, if necessary.

F-4.2 Stir the contents of beaker with a glass rod and transfer the slurry to the 250 ml graduated cylinder, ensuring that no foam (more than 2 ml) is produced and no lump paste goes into the cylinder. Repeat the transfer of the residue left in the breaker with further portions of 5 to 6 ml of water ensuring that all the matter in the beaker is transferred to the cylinder.

F-4.3 Adjust the contents in the cylinder to 50 ml by adding sufficient water and bring the contents of the cylinder to 30 °C. Stir the contents of the cylinder with a glass rod or thermometer to ensure a uniform suspension.

F-4.4 As soon as the temperature of the contents of the cylinder reaches 30 °C, stop the cylinder and give it 12 complete shakes, each shake comprising movements shown in Fig. 1 in a vertical plane, upside down and *vice versa.* After the 12 shakes have been given, allow the cylinder to stand still for 5 min and read the volumes of:

a) foam plus water (V_1 ml), and
b) water only (V_2 ml) as shown in Fig. 2.

F-5 CALCULATION

Foaming power, ml= $V_1 - V_2$

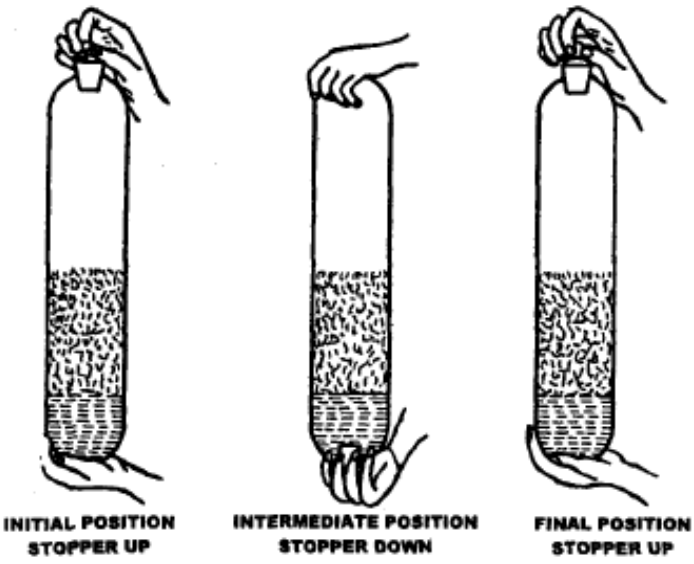

FIG. 1 ONE COMPLETE SHAKE OF CYLINDER

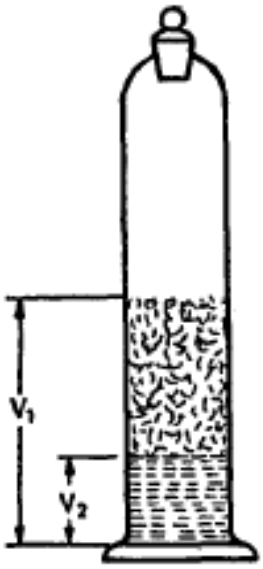

FIG. 2 MEASURMENT OF FOAM

ANNEX G

[*Clause* 5.5, *Table* 1, *Sl No*. (vi)]

DETERMINATION OF FLUORIDE ION

G-1 GENERAL

This method is suitable for the determination of water soluble fluoride species in toothpaste, including free fluoride and hydrolysable complexes, for example, sodium mono fluorophosphate.

G-1.1 Principle

Water soluble species are converted to fluoride ion by acid hydrolysis. The fluoride ion activity is then determined potentiometrically with the help of fluoride ion sensitive electrode.

G-2 APPARATUS

G-2.1 *p*H Meter (Potentiometer) — Scale readable to ± 0.5 m V or better.

G-2.2 Fluoride Ion Sensitive Electrode — Orion 94-09 or similar.

G-2.3 Single Junction Reference Electrode — Orion 90-0.1, or similar, with filling solution.

G-2.4 Magnetic Stirrer

G-2.5 Polythene/Polypropylene Beakers and Volumetric Flasks — 100, 250 ml and pipettes.

G-2.6 Semi-log Graph Papers — 2/3 cycles.

G-3 REAGENTS

G-3.1 Sodium Fluoride (Analytical Grade)

G-3.2 Trisodium citrate (Analytical Grade)

G-3.3 Sodium chloride (Analytical Grade)

G-3.4 Hydrochloric acid (Analytical Grade) — l M.

G-3.5 Sodium Hydroxide — l M.

G-3.6 Sodium Acetate Trihydrate (Analytical Grade)

G-3.7 Glacial Acetic Acid

G-3.8 TISAB L (Total Ionic Strength Adjusting Buffer) Solution — Dissolve 294 g trisodium citrate, 29 g sodium chloride and 68 g sodium acetate trihydrate in 600 ml of hot water. Cool, adjust to *p*H 6.4 with glacial acetic acid. Dilute to 1 litre with distilled water.

G-3.9 TISAB LF (TISAB Containing Fluoride) — Solution

Prepare 100 ml of lmg F- /100 ml solution as described in **G-3.8**. Dissolve 294 g trisodium citrate, 29 g sodium chloride and 68 g sodium acetate trihydrate in 600 ml of hot water. Cool, pipette in 10 ml of 1mg F–/100 ml solution and adjust to *p*H 6.4 with glacial acetic

acid. Dilute to 1 litre with distilled ‘water. Store in a polythene or polypropylene bottle.

G-3.10 Fluoride Blank Solution

Take 100 ml hydrochloric acid (lM) solution in 1 litre flask and then add 200 ml sodium hydroxide (l M), by measuring cylinder. Dilute to 1 litre with distilled water and mix well.

G-3.11 Standard Sodium Fluoride Solution (0.01 mg F^- per ml)

Dry the sodium fluoride at 11O °C for 4 h and transfer accurately 0.222 g to 100 ml volumetric flask. Add distilled water to dissolve the sodium fluoride and make up to the mark (solution-X). Each ml of solution-X contains 1mg fluoride ion (F^-). Take 10 ml of this solution-X in 1 000 ml volumetric flask and make up this volume to the mark (solution Y). Each ml of solution Y contains 0.01 mg fluoride (F^-) ion. Transfer solution-X and solution-Y to polythene bottles for storing.

G-3.12 Preparation of Standard Solutions of Sodium Fluoride

Take 1, 2, 5, 10, 20, 25 ml of solution-Y (*see* **G-3.11**) in 100 ml volumetric flask marked A, B, C, D, E and F respectively. From solution X (*see* **G-3.11**), pipette out 0.5 and 1.0 ml and transfer to two separate 100 mL volumetric flasks marked as G, H .To each add 50 ml of TISAB L buffer solution and 10 ml of fluoride blank solution. Check that the pH is in the range of 6.4 * 0.1, and if necessary correct with 1MNaOH or 1 M HC1.Transfer quantitatively to a 100 ml polypropylene volumetric flask and make up the volume to 100 ml with distilled water. Now the solutions A, B, C, D, E, F, G and H are containing 0.01, 0.02, 0.05, 0.1, 0.2, 0.25, 0.5 and 1 mg of F per 100 ml respectively. Transfer the solutions to 150 ml polythene beaker for new measurement.

NOTE — Calibration curve can be plotted using any 5 consecutive concentrations depending on the expected concentration of fluoride from sample.

G-4 mV MEASUREMENT OF STANDARD SOLUTIONS OF SODIUM FLUORIDE

G-4.1 Preparation of Electrodes

Remove protective cap and soak the fluoride electrode in TISAB L F solution for 15 min.

G-4.2 Fill the reference electrode with filling solution.

G-4.3 Rinse the electrodes with de-ionized water and keep the tips immersed in TISAB L F solution until immediately before use.

G-4.4 Check that the electrodes are correctly connected to the *p*H meter.

G-4.5 Rinse the electrodes with deionized water before use and carefully blot dry with a paper tissue.

G-5 mV MEASUREMENT

G-5.1 Transfer the contents of solution A from 100 ml flask into a clean, dry 150 ml polypropylene beaker.

G-5.2 Immerse the tips of the electrodes in the solution while stirring the solution with a magnetic stirrer.

Ensure that no air bubbles adhere to the electrode surfaces.

G-5.3 Leave until the potential reading is constant. This should take approximately 2 or 3 min.

G-5.4 Record the potential reading in mV and check the temperature of the solution.

G-5.5 Rinse the electrodes with de-ionised water and blot dry with a paper tissue.

G-5.6 Repeat the procedure prescribed in **G-5.1** to **G-5.5** for solutions B, C, D, E and F to record mV of these solutions.

G-5.7 Plot the calibration graph on semi log graph paper with the mini volt reading on the linear ordinate and the final concentration of fluoride in the standard F solution on the logarithmic abscissa. The graph should be a straight line with a gradient of -57-59 mV per decade change in concentration.

G-6 TEST SOLUTION

G-6.1 Discard the first 5 cm of paste extruded from the tube and then weigh about 5 g toothpaste to the nearest mg. For non-fluoridated toothpaste, use sample weight as 10 g instead of 5g . Add approximately 30 ml hot (90-95 °C) deionized water, a small amount at a time and slurry the paste with a microspatula after each water addition.

Allow to cool. Dilute to 100 ml in a polypropylene volumetric flask and mix well.

G-6.2 Ensure that the dispersion is homogeneous and then centrifuge about 60 ml of the dispersion in a polypropylene centrifuge tube, closed with a cap to prevent evaporation, until clear. This will take about 20 min at 4 000 rpm.

***G*-6.3** Pipette 20 ml of the clear supernatant into a 250 ml round-bottomed flask.

G-6.4 Add a few anti-bumping granules then add 10 ml hydrochloric acid solution (1M approximately) by measuring cylinder. Attach a reflux condenser and boil gently for 5 min.

G-6.5 Add, almost immediately, 20 ml of l M sodium hydroxide via the condenser, rinsing down with

approximate 20 ml of distilled water. Then transfer quantitatively to a 100 ml polypropylene volumetric flask and dilute to volume with distilled water.

G-6.6 Pipette 25 ml of the clear solution prepared above into a 100 ml polypropylene beaker, add 25 ml TISAB L (solution L) and check pH. If necessary adjust to *p*H 6.4 by addition of approximately l M hydrochloric acid or l M sodium hydroxide. Transfer quantitatively into a 100 ml volumetric flask and dilute to volume.

G-6.7 Transfer the contents of 100 ml flask to a clean, dry 100 ml polythene beaker, immerse the tips of the electrode in the solution while stirring the solution with a magnetic stirrer. Ensure that no air bubbles adhere to the electrode surfaces.

***G*-6.8** Leave until the potential reading is constant (this should take two or three minutes). Record the potential reading in mV for the test solution. The reading for standard fluoride and test solutions should be taken simultaneously.

G-7 CALCULATION

A graph is plotted for concentration of F- against potential mV on a semi-logarithmic paper for standard F solutions. The potential mV is plotted on X-axis and mg of F- on Y-axis (on logarithmic scale). Read the F concentration in test solution for measured mV from this graph.

Concentration of F^- in

$$\text{toothpaste, parts per million} = \frac{2a \times 10\,000}{M}$$

where

a = mg of F^- from calibration graph for test solution; and

M = Mass of sample, in g.

ANNEX H

(*Foreword and Clause* 6)

ABRASIVITY (RDA) MEASUREMENT TEST (HEFFERREN)

H-1 SCOPE

This annex identifies the specific procedures for determination of dentifrice abrasivity using the ADA laboratory method.

H-2 SAMPLING

A representative sample shall be taken from at least two batches.

H-3 PROCEDURE

H-3.1 Standard Reference Abrasive The standard reference abrasive is from a specific lot of calcium phosphate held by the Monsanto Company[1)].

[1)]Calcium pyrophosphate is an example of a suitable product available commercially. This information is given for the convenience of users of this standard and does not constitute an endorsement by BIS of this product. A sample of the material may be obtained by contacting the company at the address below and requesting the ADA abrasion standard.

Slight shifts (< 10 percent) in abrasivity between lots have been reported.

Monsanto Company
Detergent Division
800N Lindbergh Boulevard
St Louis MO
USA 63167

H-3.2 Apparatus

H-3.2.1 *Brushing Machine* — A cross brushing machine is the apparatus of choice[1)]. The apparatus should have eight positions for holding specimens. A toothbrush shall be positioned to pass reciprocally over the mounted specimens with a designated tension on the brush while immersed in a dentifrice slurry. The distance traversed by the brush should not be longer than the brush head, so that the specimen does not lose contact with the brush. The mechanism for holding the dentifrice slurry may vary with difference machine designs, but should allow for easy removal of the slurry sample. It is important to have some mechanism for agitation of the slurry while the brushing is taking place. A convenient method to accomplish this is to attach rubber mixing vanes just below the brush head. As the brushing takes place, these vanes will prevent the abrasive from settling to the bottom of the slurry container.

H-3.2.2 *Radioactivity Detector* — The two recommended methods for determination of the radioactivity of the used dentifrice slurries are a Gieger-Muller planchet counter or liquid scintillation detector. The use of the Geiger counter requires that the samples be dried under defined controlled conditions. The liquid scintillation method has the advantage of reading directly from the slurry.

Counting should be done for a period expected to reduce the alpha value for counting error to less than

2 percent. Counting should be performed for a minimum of 1 000 counts and at least 1 min. The number of brushing strokes may be increased if counting times become too long.

H-3.3 Presentation of Tooth Specimens

H-3.3.1 *Dentin Specimens*

H-3.3.1.1 *Selection*

Human root dentin of extracted permanent teeth are used as the substrate. Single-rooted teeth that were vital at extraction should be selected. An exception, because of the small size are, mandibular incisors, these should not be used. The specimen should be at least 14 mm long and 2 mm wide at the narrow end. All roots shall be caries-free and free of anatomical defects. After extraction, the roots should be stored in neutralized 4 percent formaldehyde solution.

H-3.3.1.2 *Preparation*

Scrape the roots clean of all soft tissue and cementum. Then remove the crown and the root tips using a separating disc under a flow of water

[1)]The drawings and blue prints of the machine may be obtained from the American Dental Association.

H-3.3.1.3 *Irradiation*

For each set of eight specimens to be irradiated, add one or two extra roots for use in correction factors. Pack the specimens in 4 percent formaldehyde solution and submit to a nuclear reactor for irradiation. The neutron flux should be sufficient to produce about 1m Ci of ^{32}P beta radiation after several hours. Elevated temperatures in the reactor should be avoided. It is also advisable to shield the samples from fast neutrons and gamma radiation. Handling of the irradiated specimens should be done with care using good laboratory practice. The specimens should not be used during the first half life because of excess radiation and should be used before the end of the third half- life because of lack of activity. The half-life of ^{32}P is 14.3 days so the usable life-span of a set of teeth is 4 weeks.

H-3.3.1.4 *Mounting of specimens*

The specimens should be mounted individually in cold-cure methyl methacrylate denture resin: the type of mould used will depend upon the holder on the brushing machine. The specimens should be mounted so that they protrude above the resin surface in a buccal/lingual orientation by at least 2 mm. The brushing surface of the root shall be parallel in buccal lingual orientation to the resin holder and situated so that the brushing will take place perpendicular to the long dimension of the root. Storage of the mounted specimens should be in 4 percent formaldehyde.

H-3.3.2 *Enamel Specimens*

H-3.3.2.1 *Selection*

Selection criteria for the enamel specimens are the same as for dentin. The enamel specimens should be obtained from human maxillary incisors.

H-3.3.2.2 *Preparation*

The entire labial surface of the specimen is used after removing the root. Clean the enamel in the same way as the root.

H-3.3.2.3 *Irradiation*

Irradiation of the enamel is identical to the method used with the roots. The roots and enamel specimens may be packed together for submission to the reactor.

H-3.3.2.4 *Mounting*

Mount the enamel specimens in the same way as the roots. The labial surface shall protrude 2 mm and be parallel to the resin surface.

H-3.4 Toothbrushes

The toothbrushes used should have nylon bristles of medium hardness. The bristle ends should lie in a plane rather than in separated or end-raised tuft design. The bristle length should be about 10 mm. A 50 tuft medium-texture brush shall be used. Store the brushes in water overnight prior to their first use and then keep them in water until they are discarded. Use a new set of brushes for each set of teeth. Do not remove the brushes from the machine between runs but raise the tufts of the specimen so as ‘not to bend the bristles. At the beginning of each run, set the tension, of the brush on the specimen to 150 g using a Chatilon spring gauge or equivalent. This tension should be rechecked at least twice daily. The method of adjusting the tension will vary depending upon the type of mechanism on the brushing machine.

H-3.5 Reference Diluent

The diluent is a 0.5 percent carboxymethylcellulose (CMC) (7MF) solution in 10 percent glycerine. To prepare 1 litre of the diluent, heat 50 ml of glycerine to 60 °C and add 5g of CMC while stirring. After the mixture is homogeneous, add another 50 ml of heated glycerine and continue stirring for 60 min. Transfer the solution to a 1 litre flask and add 900 ml of distilled water. Allow to cool but continue stirring slowly overnight. To stabilize the viscosity, allow the solution to stand overnight before using. This solution is used to make up slurries of the reference abrasive or any other powder being tested.

H-3.6 Reference Abrasive Slurry

The reference material is that described above (*see* **H-3.1**). Dilute 10 g of the abrasive with 50 ml of the diluent (*see* **H-3.5**). The same ratio is used for all powders. It is possible for the reference abrasive to be used as a dentifrice, if that has to be done. It shall be made up as a 40 percent abrasive dentifrice with the rest of the constituents being conventional dentifrice components. The slurry is then made with 25 g of reference dentifrice and 40 ml of water.

H-3.7 Dentifrice Slurries

To prepare the test slurries, add 40 ml of water to 25 g of each dentifrice. For the machine, prepare eight slurries of each dentifrice. This dilution produces a final slurry volume and concentration similar to those of the reference abrasive slurry. All slurries reference and test should be used shortly after preparation and after vigorous mechanical stirring to prevent particle setting.

H-3.8 Preconditioning of Tooth Specimens

H-3.8.1 *Dentin*

To reduce the variation caused by dentin surface differences, precondition the specimens prior to each use. The preconditioning treatment consists of brushing with slurry of the reference abrasive but not taking a sample. The first time dentin specimens are used, the preconditioning should be for 6 000 strokes. Each successive daily run should begin with a shorter precondition brushing of 1 000 strokes. The tension of the toothbrush on the roots shall be 150 g. Discard the preconditioning slurries.

H-3.8.2 *Enamel*

Preconditioning of the enamel is similar to that of the dentin, except 10 000 strokes are used prior to the first use and 1 000 strokes are given at the beginning of each day.

Discard the preconditioning slurries.

H-3.9 Test Design

H-3.9.1 *Test Design for Dentin*

The test design may be either a sandwich design or a Latin square design. The sandwich design is such that a set of reference slurries is run (pre-test), followed by a second set of reference slurries (post-test) .This second set of reference slurries (post-test). This second set of reference slurries then acts as the pre-test slurries for the next test group. This continues until all the test groups are run.

The Latin square design is such that a set of reference slurries is run first. All the test groups are randomized over the eight brushing heads for the next few runs (depending on the number of test groups). Then a post test reference set of slurries is run as the final procedure.

In both test designs, the brush tension is set at 150 g and brushing is performed for 1 500 to 3 000 strokes depending on the radioactivity level of the specimens.

H-3.9.2 *Test Design for Enamel*

The test design for enamel is identical to that for dentin, except the number of strokes is 5 000 to 7 500 depending on the activity of the specimens.

H-3.10 Sampling of Slurries

The sampling of the slurries following the brushing is identical for both dentin and enamel. An aliquot of each slurry is removed immediately following brushing. The size of the aliquot will depend upon the counting method and equipment, but 3 ml is usually adequate to provide a detectable level of radioactivity. A convenient method for removing the sample is a syringe fitted with a blunt needle. Take care to ensure no carry-over between samples. This can best be done by a complete rinsing of the syringe between samples. It is also important to remove the same quantity of sample from each slurry. Dry the sample if a planchet counter system if being used to detect the radioactivity. If drying is needed, the samples should be air-dried for at least 1 h and then dried in an oven at 60 °C with forced air overnight.

H-3.11 Correction Factors

Correction factors are needed for both dentin and enamel abrasion tests when using the planchet counting method and are identically prepared in both methods. When testing dentifrices with abrasive systems different from the reference materials, the self absorption and backscattering characteristics of the abrasives for beta radiation may also differ. Real differences in abrasivity may then be significantly distorted. The correction factor is a means to reduce this variable. The correction factor is determined differently depending on the counting method used.

H-3.11.1 *Preparation of Correction Factor Slurries for Geiger-Muller Planchet Counting*

Dissolve one piece of irradiated dentin (or enamel) in 5 ml of concentrated HC1. Transfer the solution to a 250 ml volumetric flask and add water to the mark. Add 1.0 ml of this radioactive solution to slurries of the reference abrasive and to each of the test abrasives prepared in the same manner as in the test. To neutralize the acid, add 1.0 ml of 0.5 mol/NaOH. Mix the slurries thoroughly, sample and dry the samples along with those from the test runs. Do not brush with these correction factor slurries.

These samples are counted along with the test samples.

H-3.11.2 *Calculation of Correction Factors*

The correction factor ***Cf*** to be applied to all values of the test sample is calculated as follows:

$$Cf = \frac{Mean\ counts\ \ for\ 4\ reference\ samples}{Mean\ counts\ \ for\ 4\ test\ samples}$$

H-3.11.2.1 *Correction factors for liquid scintillation counting*

The correction is with regard to the amount of sample mixed with the scintillation cocktail. Each sample is weighed and the net count per minute (CPM) is divided by the mass to get a net CPM per gram of slurry. These net CPM per gram of values are then used in calculating abrasivity in place of net CPM values in **H-3.12**, and there is no C*f* term.

H-3.11.2.2 *Correction factors for liquid scintillation detection*

Self-absorption and backscatter are less of a concern because of the liquid medium being used. Most modern liquid scintillation equipment will automatically colour-correct, so this is not a problem. The differences in mass of the samples do need to be accounted for in the calculation. To do this, each sample taken after brushing needs to be weighed to an accuracy of 0.01 g.

H-3.11.2.3 *Applying the correction factor*

Before calculating the relative abrasion values, the net CPM of each slurry is divided by the mass of the slurry used, to get a net CPM per gram of slurry. These values are then used in the calculation of relative abrasive values.

H-3.12 Calculation of Abrasivity Using Gieger- Muller Counting

H-3.12.1 *Dentin Abrasivity*

The dentin abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean Reference net CPM =

$$\frac{Pre-net\ CPM\ +\ Post-net\ CPM}{2}$$

Dentifrice abrasivity =

$$\frac{Cf\times 100\times test\ dentifrice\ Net\ CPM}{Mean\ reference\ net\ CPM}$$

H-3.12.2 *Enamel Abrasivity*

The enamel abrasivity of the test dentifrices for abrasives is calculated as follows:

Mean reference net CPM =

$$\frac{Pre-net\ CPM\ +\ Post-net\ CPM}{2}$$

Dentifrice abrasivity =

$$\frac{Cf\times 10\times test\ dentifrice\ Net\ CPM}{Mean\ reference\ net\ CPM}$$

H-3.13 Calculation of Abrasivity using Liquid Scintillation

H-3.13.1 *Dentin Abrasivity*

The dentin abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean reference net CPM per gram =

$$\frac{Pre-net\ CPM\ \ per\ gram+\ Post-net\ CPM\ \ per\ gram}{2}$$

Dentifrice Abrasivity =

$$\frac{100\times test\ dentifrice\ Net\ CPM\ \ per\ gram}{Mean\ reference\ net\ CPM\ \ per\ gram}$$

H-3.13.2 *Enamel Abrasivity*

The enamel abrasivity of the test dentifrices (or abrasives) is calculated as follows:

Mean reference net CPM per gram =

$$\frac{Pre-net\ CPM\ \ per\ gram+\ Post-net\ CPM\ \ per\ gram}{2}$$

Dentin Abrasivity =

$$\frac{10\times test\ dentifrice\ Net\ CPM\ \ per\ gram}{Mean\ reference\ net\ CPM\ \ per\ gram}$$

NOTES

Centres for measuring toothpaste abrasivity via RDA route:

1 Indiana University, School of Dentistry
Oral Health Research Institute
415 Lansing Street
Indianapolis, Indiana 46202
USA

2 Missouri Analytical grade Laboratories

Marcus Research Laboratories, lNC
1820 Delmar Boulevard
St Louis,MO63103-1798
USA

ANNEX J

(*Foreword*)

COMMITTEE COMPOSITION

Cosmetics Sectional Committee, PCD 19

Organization	*Representative(s)*
Drugs Controller General (INDIA), Delhi	Dr V. G. Somani (***Chairman***)
All India Cosmetic Manufacturers Association, Mumbai	Ms Kajal Anand Dr Virendra V. Chavan (*Alternate*)
Chemstar Limited, Mumbai	Shri Sunil Joshi
Cavinkare Private Limited, Chennai	Dr T. Kumar Dr Gireesh Kumar (*Alternate* I) Dr S. Sankar Kalidas (*Alternate* II)
Central Drugs Standard Control Organization (CDSCO), Delhi	Dr S. P. Shani
Central Drugs Testing Laboratory (CDTL), Chennai	Ms C. Vijaya Lakshmi Dr J. Uma Maheswari (*Alternate*)
Consumer Voice, New Delhi	Shri H. Wadhwa
CSIR Indian Institute of Toxicological Research, Lucknow	Dr A. B. Pant Dr R. S. Ray (*Alternate*)
Central Drugs Testing Laboratory (CDTL), Mumbai	Dr Raman Mohan Singh Shrimati S. U. Warde (*Alternate* I) Shrimati Sujata S. Kaisare (*Alternate* II)
Colgate Palmolive (India) Limited, Mumbai	Dr Manas V. Vyas Shrimati Shruti Hardikar (*Alternate* I) Shri Purushottam Jadhav (*Alternate* II)
Consumer Guidance Society of India, Mumbai	Dr Sitaram Dixit Dr M. S. Kamath (*Alternate*)
Dabur India Limited, Sahibabad	Dr Prasun Bandyopadhyay Dr S. K. Luthra (*Alternate* I) Shri Shivaji Rai (*Alternate* II)
Directorate of Food and Drugs Administration, Goa	Ms Jyoti J. Sardessai
Drugs Control Department, Delhi	Shri A. K. Nasa Shri K. R. Chawla (*Alternate*)
Envisbe Solutions Pvt. Limited, Mumbai	Shri Benedict M. Mascarenhas
Essential Oil Association of India (EOAI), Noida	Shri Ajay K. Jain
Food Safety and Drug Administration, Lucknow	Dr Anita Bhatnagar Jain Shri Dinesh Kumar Tiwari (*Alternate*)
Food and Drugs Control Administration Gujarat, Gandhinagar	Dr H. G. Koshia Shri V. R. Shah (*Alternate*)
Food and Drugs Administration Haryana, Panchkula	Shri Narender Kumar Ahooja Shri Manmohan Taneja (*Alternate*)
Food and Drugs Administration Maharashtra, Mumbai	Shri O. S. Sadhwani
Fragrance and Flavours Association of India, (FAFAI), Mumbai	Shri Hasmukh Patel

Organization	*Representative(s)*
Galaxy Surfactants Limited, Mumbai	Shri R. K. Singh Shri Sagar Trailokya (*Alternate* I) Shri Pramod Sabat Trailokya (*Alternate* II)
Godrej Consumers Products Limited, Mumbai	Ms Rupinder Kaur Rawat Dr Manoj Gaur (*Alternate*)
Hindustan Lever Limited (HUL), Mumbai	Ms Vrinda Rajwade
Hygienic Research Institute Private Limited, Mumbai	Dr Jayashree Anand Shri Manoj Sarkar (*Alternate*)
Indian Pharmacopoeia Commission (IPC), Ghaziabad	Dr Anil Kr Teotia Dr Manoj Kr Pandey (*Alternate*)
ITC R & D Centre, Bengaluru	Dr Gurubasavaraja Km Dr James Bhaskar (*Alternate* I) Dr John Bosco Stanislaus (*Alternate* II)
Indian Beauty and Hygiene Association (IBHA), Mumbai	Ms Malathi Narayanan
Johnson and Johnson Limited, Mumbai	Dr Dilip Tripathi Shri Rajneesh Kumar (*Alternate*)
Kelkar Education Trusts (KETS) Scientific Research Centre, Mumbai	Dr S. S. Barve
Loreal India Private Limited, Mumbai	Ms Veena Balgi Ms Rupali Turakhiya (*Alternate*)
Marico Limited, Mumbai	Dr Mitali Hedge Dr Sudhakar Mhaskar (*Alternate* I) Shri Prabodh S. Halde (*Alternate* II)
Mikasa Cosmetics Limited, Ahmedabad	Ms Trupti Patel
Ministry of Micro, Small and Medium Enterprises (MSME), Delhi	Dr Arun Kumar Dr Izzatullah (*Alternate*)
Ministry of AYUSH, Delhi	Dr D. C. Katoch
Procter and Gamble, Mumbai	Shri Girish Parhate
PETA India, Mumbai	Shri Manilal Valliyate Ms Dipti M. Kapoor
The Himalaya Drug Company, Bengaluru	Dr Sundaram Ramachandran Dr Krishnan Sriraman (*Alternate*)
Voluntary Organization In Interest of Consumer Education (VOICE), Delhi	Dr M. A.U. Khan
Bureau of Indian Standards, Jammu	Shrimati Nisha Bura
BIS Directorate General	Shrimati Nagamani. T, Scientist 'E' and Head (PCD) [Representing Director General (*Ex-officio*)]

Member Secretary

Shrimati D. Uma
Scientist 'D' (PCD), BIS

Decorative and Miscellaneous Cosmetics Subcommittee, PCD 19 : 4

Organization	*Representative(s)*
Regional Drugs Testing Laboratory, Chandigarh	Dr R. A. Singh (***Convenor***)
Arbro Pharmaceuticals Limited, New Delhi	Shri Sourab Arora
Colgate Palmolive India Limited, Mumbai	Shri Manas V. Vyas Shrimati Shruti Hardikar (*Alternate* I) Shri Purushottam Jadhav (*Alternate* II)
Consumer Education and Research Centre, Ahmedabad	Shri H. S. Tripathi
Consumer Guidance Society of India, Mumbai	Dr Sitaram Dixit Dr M. S. Kamath (*Alternate*)
Dabur India Limited, Sahibabad	Dr S. K. Luthra Shri Prasun Bandyopadhyay (*Alternate* I) Shri Shivaji Rai (*Alternate* II)
Directorate of Drugs Control, West Bengal, Kolkata	Shri Sajal Kumar Roy Chowdhury
Food and Drug Administration, Mumbai	Shri O. S. Sadhwani
Food and Drugs Control Administration, Ahmedabad	Shri H.G. Koshia Shri V. R. Shah (*Alternate*)
Godrej Consumer Products Limited, Mumbai	Dr Rupinder Kaur Rawat Dr Manoj Gaur (*Alternate*)
Hindustan Unilever Limited, Mumbai	Dr Vrinda Rajwade
Indian Pharmacopoeia Commission, Ghaziabad	Dr Anil Kr Teotia Dr Manoj Kumar Pandey (*Alternate*)
Institute of Chemical Technology, Mumbai	Dr Amit P. Pradeep
Johnson and Johnson Private Limited, Mumbai	Dr Dilip Tripathi Shri Rajneesh Kumar (*Alternate*)
Koel Colours Private Limited, Mumbai	Shri D. Desai Shri Shailendra Shripannavar (*Alternate*)
Loreal India Private Limited, Mumbai	Ms Veena Balgi Ms Rupali Turakhiya (*Alternate*)
Procter and Gamble India, Mumbai	Shri Girish Parhate
Reckitt Benckiser India Private Limited, Mumbai	Dr Pooja Sharma
In Personal Capacity	Shri Vinay Kumar Singh

(*Continued from second cover*)

A scheme for labelling environment friendly products to be known as ECO Mark (optional) has been introduced at the instance of the Ministry of Environment, Forests and Climate Change (MoEF&CC). The ECO Mark shall be administered by the Bureau of Indian Standards (BIS) under the *Bureau of Indian Standards Act*, 2016 as per the Resolution No. 71 dated 20 February 1991 and No. 768 dated 24 August 1992 published in the Gazette of the Government of India. For a product to be eligible for ECO Mark it shall also carry Standard Mark of BIS for quality, besides meeting additional environment friendly (EF) requirements. For this purpose, the Standard Mark of BIS would be a single mark being a combination of the ISI Mark and the ECO logo. The requirements for the ECO friendliness will be additional, manufacturing units will be free to opt for Standard Mark alone also.

The composition of the Committee responsible for formulation of this standard is given at Annex J.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 "Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: PCD 19 (16573).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	: Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002	2323 7617, 2323 3841
Eastern	: 1/14 C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi, KOLKATA 700054	2337 8499, 2337 8561, 2337 8626, 2337 9120
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg, CHANDIGARH 160019	265 0206, 265 0290
Southern	: C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442, 2254 2519, 2254 2315
Western	: Manakalaya, E9 MIDC, Marol, Andheri (East), MUMBAI 400093	2832 9295, 2832 7858, 2832 7891, 2832 7892

Branches : AHMEDABAD. BENGALURU. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. DURGAPUR. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. JAMMU. JAMSHEDPUR. KOCHI. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAIPUR. RAJKOT. VISAKHAPATNAM.

Published by BIS, New Delhi